Support for Research and Protocol Development

1. add a protocol accrual management section in protocol template
   -create overall framework that is adaptable for each center
   -include categories for companion studies/epidemiology, correlative science, QOL, CAM
   -include research base of cooperative groups and SPORES
   -include SPORE investigators and cooperative group chairs to get to what is really being done and how to integrate together
   -PI registry
   -create CDE / common terms
   Deborah Collyar

2. Assist PI with creating an accurate budget- we have problems with PIs who create their own budget, get approval, start to accrue and run out of money because their budget was not accurate

3. circular model too simplistic
   Christa

4. Data registrar
   -understanding the size of the pool of subjects available when developing competing protocols.

5. CRE/DSMB requirement for protocol approval and monitor
   -IRB submission status tracking
   -multi-center consent form

6. Statistician
   -work with PI/COI to ensure that proposed protocol has sufficient statistical power
   Informatician
   -Work with PI/COI to ensure that systems are available to provide necessary data collection to support research questions.

7. CRF development/ review
   -should CRF be considered as part of protocol development?
   Investigator registry- NCICB/FDA effort
   -Use case- a CTMS should be able to receive a structured protocol representation message and be able to instantiate a study- to the detail of study calendar definition

8. Clinical Research organization role- what does a CRO do to get a protocol started?
   -Sponsor role- drives protocol design and protocol reporting requirements

9. Change management issue: PI's are used to writing text protocols

10. Milestones for protocol regulatory activity ie. Status of protocol vs. needs for protocol approval needs

Support for CT Enrollment and Management

11. oncologist/ remove ITS from trials
    -oncologist/ uses clinical data to modify treatment
    -versions of protocols- modifications after recruitment study starts
    -data managers/ set up CTMS and determine informatics "needs"

12. Also include cooperative groups and SPORES to see what they are doing and to share and maybe pilot caBIG tools with them
    -Protocol registry- use or expand cancer.gov/ PDQ
    -create an accrual management section to help develop a planned approach to delivering c.t.s.

13. Module for patient screening process criteria for protocol vs. patient information

14. Quality assurance- metrics assessing protocol implementation/efficiency

15. Patient eligibility screening based on protocol requirement
    - patient visit scheduling

16. Include PT recruitment/advertisement of trial
    -send information about clinical trial to various sources that a pt/MD will consult
    -Include Tumor registry- at what point sharing of trial information?
    -Tumor Registry:
    -PT identified via protocol screening, data shared with tumor registry
    -PT with information in tumor registry has updates by looking at clinical system updates

Support of CT Reporting and Administration

17. some type of protocol evaluation form/process to identify interest and problems in accrual

19. Committee report
    -data safety monitoring consulting
    -quality assurance committee
    -protocol review
20. AD-HOC reporting mechanism possible query tool incorporation
    - standardized reporting module for government and regulatory reporting

21. CDUS to CTEP
    -CTMS/Theradex
    -ECTD to FDA

22. data/ safety monitoring reports
    -QA reports ongoing
    -Administrative items- Screening v. Accrual, reasons for no enrollment, protocol-centered information
    -study coordinators need to query for a lot of issues, almost an ad-hoc capability

Support for Data Mining and Analysis

23. Support for publications/ presentations
    -presentation at consensus meetings

24. Incorporate other initiatives into the system ie. SPORE, HIPPA-IRB, EDRN
    -share everyone's systems and tools so that they can be considered
    -information to and from other key groups that are involved with CCs: ie. EDRN, SPORE, cooperative groups, clinical PO's, etc.

25. need a link back to patient management from analysis "real time" decision support
    -interim analysis
    -pooled analysis
    -journals/ evaluate the study design for publication determination